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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,506	07/15/2005	John L. Holahan	SITH 9317W1	5924
1688 7590 03/20/2009 POLSTER, LIEDER, WOODRUFF & LUCCHESI 12412 POWERSCOURT DRIVE SUITE 200 ST. LOUIS, MO 63131-3615				
EXAMINER				
JONES, DAMERON LEVEST				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
03/20/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,506

Applicant(s)

HOLAHAN, JOHN L.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-15, 29-33, 39-45 and 52-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-3, 6-15, 29-33, 39-45, 52-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

RESTRICTION INTO GROUPS

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 6-8, and 52, drawn to a treatment for patients afflicted with dysphagia and another disease or injury.

Group II, claim(s) 9-13, drawn to treatment for dysphagia which comprises feeding prepackage and prethickened liquid food composition.

Group III, claim(s) 14 and 15, drawn to a method of increasing the liquid consumption of a patient with dysphagia.

Group IV, claim(s) 29-33 and 53, drawn to a process of diagnosing and managing dysphagia wherein a rheology system is utilized as set forth in independent claim 29.

Group V, claim(s) 39-45, drawn to a process for producing a homogenous single phase thickened beverage.

Group VI, claim(s) 54 and 55, drawn to a process for diagnosing and treating dysphagia which involves the method as set forth in independent claim 54.

Group VII, claim(s) 56, drawn to a prepackaged and prethickened liquid food as set forth in independent claim 56.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: (1) the treatment inventions (e.g., Groups I and II) are distinct from one another because in one case a subject has dysphagia, but in the other, the subject has dysphagia and another

disease/injury that is different from dysphagia. Possible other diseases/injuries include throat injury, surgery, stroke, multiple sclerosis, Asperger syndrome, esophageal cancer, laryngeal cancer, Chagas disease, celiac, cystic fibrosis, Huntington's disease, Niemann-Pick disease, neurological conditions, Alzheimer's disease, Parkinson's disease, obesity, Riley-Day syndrome, high cholesterol, corn allergies, corn sensitivities, scleroderma, and diabetes. (2) Another distinct invention is a method for increasing the liquid consumption of a subject with dysphagia as set forth in independent claim 14. (3) The invention also contains claims directed to a process for diagnosing and managing dysphagia as set forth in independent claim 29. (4) Another embodiment of the instant invention is a process for the production of homogenous single phase thickened beverage as set forth in independent claim 39. (5) Still another embodiment is the process for diagnosing and treating dysphagia which utilizes a radiological compound thickened as set forth in independent claim 54. (6) A final embodiment involves a prepacked and prethickened liquid food as set forth in independent claim 56. Thus, the claims are directed to distinct inventions requiring different limitations and a search of the prior art. The inventions neither anticipate nor render obvious the other inventions having different claim limitations.

ELECTION OF SPECIES

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so

linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows as set forth above.

4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). The claims are deemed to correspond to the species listed above.

Note: Applicant is respectfully requested to elect a single disclosed species from the elected group above for search purposes. The species should include, if appropriate for the elected group, a specific other disease/injury (e.g., if Applicant selects neurological condition, then identify a specific neurological condition); and a soluble food fiber thickener.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons set forth above.

6. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.
7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.
8. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

REJOINDER PARAGRAPH

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

March 16, 2009